April 2007

# Arizona State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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## Board Member News

Congratulations to Steven Haiber, the newest pharmacist member of the Arizona State Board of Pharmacy. Steve was appointed by Governor Janet Napolitano on January 15, 2007, and will serve until January 23, 2012. He is a graduate of the University of Maryland and is currently director of pharmacy practice at Express Scripts in Tempe, AZ. Steve spends his spare time playing golf and hiking.

Thank you to outgoing Board member Dr Linda McCoy. She participated as fully as any Board member in memory and was always involved in pharmacy activities with other professional societies and groups. It was often wondered how she was able to be in so many places and wear so many professional "hats" so well. Must have been the cool, clean air up in the Chino Valley.

## New Technology – Online Applications Available

By the time you get this *Newsletter,* persons applying for a facility permit from the Arizona Board of Pharmacy will have been applying via the Internet for at least two weeks. Beginning March 7, 2007, applications for new pharmacies, nonprescription drug retailers, wholesalers, manufacturers, and compressed medical gases were available to be submitted online.

It is our plan to provide similar processes that will allow applicants for licensees such as pharmacists, technicians, and interns to apply online, hopefully by the end of this fiscal year (June 30, 2007). The new Web-based interface not only offers an alternative to mailing paper forms, but allows applicants to attach documents in PDF or Word formats where applicable and to pay using a credit card. The interface also allows applicants to receive their permits via the e-mail addresses they provide. The Board is pleased to announce this new electronic convenience as a result of its ongoing relationship with IBM and looks forward to more innovation in the future. Please visit our Web site at *www.azpharmacy.gov* or *http://az.gov/webapp/pharmacy* for more details.

## May 1, 2007 Controlled Substance Inventory

A friendly reminder for those of you who perform your controlled substance inventory on May 1 each year, the applicable statutes and rules are as follows:

Arizona Revised Statutes §36-2523: A person who holds a permit to operate a pharmacy issued under title 32, chapter 18 shall inventory Schedule II, III, IV, and V controlled substances as prescribed by federal law.

Please see 21 CFR 1304 or the following for required elements of the inventory:

Arizona Administrative Code R4-23-1003: The inventory shall be on May 1 of each year or an annual date chosen by the permit holder and filed with the Board. This inventory and any other required controlled substance inventory shall:

a. Include an exact count of all Schedule II controlled substances;
b. Include an exact count of all Schedule III - Schedule V controlled substances or an estimated count if the stock container contains fewer than 1,001 units;
c. Indicate the date the inventory is taken and whether the inventory is taken before opening of business or after close of business for the pharmacy;
d. Be signed by:
   i. The pharmacist-in-charge; or
   ii. For other required inventories, the pharmacist who does the inventory;
e. Be kept separately from all other records; and
f. Be available in the pharmacy for inspection by the Board or its designee for not less than two years.

## Proposed Board Office Relocation

The Arizona Department of Administration has identified the Board of Pharmacy as the prime candidate for

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## FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at *www.fda.gov/medwatch/report/hcp.htm*. Reports can also be made by phone at 1-800/FDA-1088.

## Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.

During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at *www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.*

## Changes in Medication Appearance Should Prompt Investigation

*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

As the number of generic products continues to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**® (letrozole) but instead received the estrogen replacement product **femhrt**® (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

## FDA Launches CDERLearn Educational Tutorial on MedWatch

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at *www.connectlive.com/events/fdamedwatch*. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at *www.fda.gov/cder/learn/CDERLearn/default.htm*.

## ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at *www.buprenorphine.samhsa.gov*.

## Deadline Approaches for Pharmacists to Use NPI Numbers

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require pharmacists to begin using the National Provider Identifier (NPI) by May 23, 2007. These provisions are intended to improve the efficiency and effectiveness of the electronic transmission of health information. Pharmacists can apply online or print an application for an NPI at *https://nppes.cms.hhs.gov*.

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relocation to the Capitol Mall in downtown Phoenix, AZ. According to sources there, the move has a 98% probability, and the other 2% only exists due to the unpredictable nature of government generally and of politics specifically. The move is free to the Board, but remodeling the existing space to suit may cost as much as $80,000. The effect on the Board budget is, shall we say, "substantial." Somehow we will get it done and be in the new quarters by July 1 of this year.

The new address will be 2nd Floor, Capitol Tower, 1700 W. Washington, Phoenix, AZ, 85007.

## *Disciplinary Actions – Board of Pharmacy (Actions since January 2007* Newsletter*)*

*Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).*

### Disciplinary Actions – Other Health Care Licensing Boards

**Chloupek, W. Neil (MD 4553)** – License Revoked. Effective October 16, 2006.

**Denicole, Michael (DO 2103)** – Amended Order: Restricted From Prescribing Schedule I, II, III, IV, and V Drugs. Effective November 29, 2006.

**Guerricacchevarria, Deborah (RN051679 & AP0219)** – Emergency Suspension of License Pending Hearing. Effective January 26, 2007 (aka Guerricaechevarriagregg, Deborah; Guerry, Debi).

**Halter, Mitchell R. (MD 29626)** – Interim Consent Agreement – Respondent Shall Not Perform Implantations or Spinal or Epidural Sensory Anesthesia. Effective October 12, 2006.

**Handeguand, Thomas (DO 2220)** – Amended Order: Restricted From Prescribing Schedule II and III Drugs. Effective November 29, 2006.

**Kennedy, Ethan O. (DO 3123)** – Amended Order: Respondent May Prescribe, Administer, and/or Dispense Schedule III hydrocodone or codeine Preparations in his Practice Setting. Effective October 23, 2006.

**Leung, King T. (MD 10262)** – Interim Finding of Fact – License Suspended Pending Formal Hearing. Effective November 30, 2006.

**Meyers, Martin L. (MD 27917)** – License Surrendered to Board. Effective December 7, 2006.

**Qureshi, Mohammad Zafar (MD 8269)** – Interim Consent Agreement – Respondent and Practice Shall Cease Using Injectable Toradol® or Any Other Alcohol Containing Substances. Effective November 5, 2006.

**Remen, Kenley M. (MD 30159)** – License Revoked. Effective December 13, 2006.

**Soundararajan, T.S. (MD 15670)** – Letter of Reprimand. Effective October 12, 2006.

### Disciplinary Actions – Pharmacists

**Branson, Thomas (S04208)** – Two Years Probation. Effective February 14, 2007.

**Breeding, Anthony (S15856)** – Five Years Probation (Continuance of Consent Issued as an Intern November 10, 2006). Effective January 25, 2007.

**Lieu, Van (S15026)** – Six Months Probation and Fine. Effective January 25, 2007.

**Likes, Keith (S07450)** – Six Months Probation, Fine, and 11 continuing education (CE). Effective January 25, 2007.

**Mai, Michelle (S12319)** – Suspension Lifted. Two Years Probation. Effective January 25, 2007.

**Massrock, Peter (S12166)** – 30-Day Probation & Fine. Effective January 25, 2007.

**Okamoto, Paul (S05482)** – 30-Day Probation and Fine. Effective January 25, 2007.

**Sanchez, Paul (S11492)** – Probation Until Completion of eight CE and Payment of Fine. Effective January 25, 2007.

**Soni, Bhavesh (S13212)** – Six Months Probation, 11 CE and Fine. Effective November 9, 2006.

**Yoha, Mike (S13936)** – License Revoked. Effective February 14, 2007.

### Disciplinary Actions – Pharmacy Technicians

**Begay, Caroline (T00657)** – 30-Day Probation and Fine. Effective January 25, 2007.

**Cortes, Angela (T08246)** – 30-Day Suspension, Followed by one Year Probation and Fine. Effective January 25, 2007.

**Norman, Michele (T05124)** – License Revoked. Effective January 25, 2007.

**Pipitan, Consuelo (T00818)** – Three Years Probation and six CE. Effective January 25, 2007.

**Solano, Ricky (T07398)** – License Revoked. Effective November 8, 2006.



The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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